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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,171	12/01/2000	Brent R. Constantz	CORA-007CIP	3702

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EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,171

Applicant(s)

CONSTANTZ, BRENT R.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12, 14-19 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12, 14-19 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed August 4, 2004 have been received and entered into the application.

Action Summary

The objection of specification as introducing new matter is hereby expressly withdrawn in view of Applicant's response.

The rejection of record of claims 1-5, 7-12 and 14-19 rejected under 35 U.S.C. 102(e) as being anticipated by Hausheer et al. (U.S.5,902,610) of record is being maintained for the reasons stated in the previous office action.

Applicant's amendment necessitated new rejection presented in this Office action.

Claim Rejections - 35 USC § 102

Claims 21-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Hausheer et al. (U.S.5,902,610) of record evidenced by The Merck Index (Tenth Edition).

Hausheer et al. teach a pharmaceutical formulation comprising a solution of an inorganic acid solution (i.e. hydrochloric acid) and a salt (i.e. NaCl), suitable for parenteral administration (i.e. intraperitoneal, subcutaneous, intra-arterial, intravenous) by mean administration by hypodermic needle or **catheter**. Hausheer et al. teach the

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final pH of the solution was adjusted by adding 1N hydrochloric acid. (column 24, lines 5-7, column 33, Example 18 and 19). Hausheer et al. teach the formulation can be combined with cisplatin (cytotoxic agent). (abstract).

Applicant's recitation in claims 21-30 of an intended use of catheter for dynamically introducing the solution and aspirating the solution does not represent a patentable limitation since such fails to impart any physical limitation to the composition in the prior and there is no reason why the same "catheter" utilized by the prior is not capable of performing the intended use since the "kit" claimed by the Applicant comprises same solution (1N hydrochloric acid) having a same subphysiologic pH and a fluid delivery device, i.e. catheter. The "kit" to be employed would be inherent upon administration of the composition (1N hydrochloric acid and a salt) with the catheter as taught by Hausheer et al.

Merck Index teaches 1N hydrochloric acid has pH value of 0.10.

Merck Index is brought in to show 1N hydrochloric acid utilized by Hausheer et al has the same pH claimed by Applicants.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102(e).

Response to Arguments

Applicant's arguments filed on August 4, 2004 have been fully considered but they are not persuasive. Applicant argues that the claimed kits are limited such that the

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fluid delivery device must be one that is able to introduce a fluid to and simultaneously remove it from a vascular site. This is not persuasive because Hausheer et al. teaches same fluid delivery device “catheter” as claimed by the Applicants and “simultaneously remove the fluid from a vascular site” does not represent a patentable limitation since such fails to impart any physical limitation to the composition. Given the broadest interpretation of claims, Hausheer et al. clearly teaches same fluid delivery device (catheter) claimed by the Applicants therefore Hausheer et al. is too capable of performing the intended use of “simultaneously removing the fluid from a vascular site” without any physical limitation to distinguish the same “catheter” being utilized.

Applicant next argues new claims 21 to 30 all require the solution to have a pH of 0 to 1 and Hausheer solution has a pH of 2 to 6 and new claims 21 to 30 are not anticipated by Hausheer. This is not persuasive because Hausheer 's formulation comprises a solution (hydrochloric acid 1N) having pH of 0.1 which is encompasses by claimed range 0 to 1. Therefore, claims 21–30 are clearly anticipated by Hausheer et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of 20 April 2004 is deemed proper and asserted with full force and repeated herein applicants' convenience.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 7-12 and 14-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Hausheer et al. (U.S. 5,902,610) of record.

Hausheer et al. teach a pharmaceutical formulation comprising a solution of an inorganic acid solution (i.e. hydrochloric acid) and a salt (i.e. NaCl), with pH range of 2 to 6, suitable for parenteral administration (i.e. intraperitoneal, subcutaneous, intra-arterial, intravenous) by means of administration by hypodermic needle or **catheter**.

Applicant's recitation in claims 1, 8 and 15 of an intended use of catheter for dynamically introducing the solution and aspirating the solution does not represent a patentable limitation since such fails to impart any physical limitation to the composition in the prior and there is no reason why the same "catheter" utilized by the prior is not capable of performing the intended use since the "kit" claimed by the Applicant

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comprises same solution having a same subphysiologic pH and a fluid delivery device, i.e. catheter. The "kit" to be employed would be inherent upon administration of the composition (hydrochloric acid and a salt) with the catheter as taught by Hausheer et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102(e).

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
October 25, 2004